including the amendments to Claims 1, 4, 8 and 11 which are disclosed in Example 7 of the present application, and thus no new matter has been added to the application.

In the Official Action, Claims 1, 6, 8, 11 and 12 were rejected under 35 U.S.C. §112, second paragraph, for reciting the term "includes", and this objection is overcome in that the term "includes" has been replaced with the term "comprises."

In the Official Action, Claims 1-12 were rejected under 35 U.S.C. §103(a) as being obvious over Howard (U.S. Patent No. 4,335,116). Applicants now respectfully traverse this rejection for the reasons as set forth below.

The Examiner states that the *only* difference between Howard and the instant claims is that *the prior art teaches complex solutions that are made individually and may require more time in processing the formulation.* However, Applicants respectfully submit that this is incorrect as not only the time and the practicality are important, but the crucial difference is the higher concentrations achievable by the method of claim 1. The higher concentrations are essential to produce an injection having a manageable volume. For example, according to the method of the present claim 1, it is possible to obtain, per the examples in the described applications, the manufacture of a product containing (per ml) 20 mg zinc, 20 mg manganese, 10 mg copper, 5 mg chromium and 5 mg selenium. In comparison, example 1 of Howard (column 7) produces a product containing (per ml) only 4 mg zinc, 3 mg, manganese, 1 mg copper, 0.5 mg chromium and 5 mg selenium. The only mineral of same concentration is selenium. A comparison of the injections required to supplement the materials is of critical importance. For instance, the following Table 1 shows the amount of product to be injected to obtain the same level of supplementation between the present claim 1 and the method of Howard:

Table 1: Quantity of product required to supplement same minerals quantities

Mineral to be supplied	Required quantity of product of present claim 1	Required quantity of product of Howard
100mg Zinc	5 ml	25 ml
100mg Manganese	5 ml	33 ml
50mg Copper	5 ml	50 ml
25mg Chromium	5 ml	50 ml
25mg Selenium	5 ml	5 ml

Thus, with the exception of selenium, it would be required to inject between 25 and 50 ml of the product of Howard to achieve the same level of supplementation as with the product of the present claim 1. Furthermore, a safe subcutaneous parenteral injection is normally accepted as at most 10 ml per injection. The method of Howard thus provides a non-practical product, whereas the method of the present claim 1 provides a practically applicable product.

In addition, the process according to the present claims enables the manufacture of a product comprising high concentrations. This is impossible according to the method of Howard. For instance, preparing a mixture containing 25 mg/ml zinc plus 25 mg/ml manganese plus 25 mg/ml copper, would require mixing equal volumes containing 75 mg/ml each of zinc, manganese and copper, which would be impossible, because 75 mg/ml exceeds the solubilities of any of the individual components. Thus, the product according to Howard cannot make a meaningful contribution to mineral status due to the low concentrations.

A further difference between the present claim 1 and the prior art, is that Howard (column 5, line 15) utilizes tetrasodium salt of EDTA which results in an excess of sodium ions, whereas Laurie et al utilizes EDTA acid with sodium hydroxide or the disodium salt of EDTA, thus enabling a product free of contaminant.

Even further, the method of Howard requires the use of stock solutions, making it extremely cumbrous, tedious and unfit for mass production, especially where solutions of variable composition and concentration are concerned. In one preferred embodiment of the present method, the reactants, in solid form, are added one after the other to water in the same reaction vessel, and thus a mixture of any number of complexed minerals (limited only by the possibilities) and of any concentration each (limited only by its solubility) can be prepared.

Thus the present method is a unique one-stop (continuous) process to prepare solutions of variable composition and concentration, instantly according to prescription, without the present of contaminants.

Further differences between the present claim and Howard are that the present method utilize selenium ion in its raw inorganic form, i.e. *Sodium* Selenite (Na_2SeO_3), whereas Howard (claim 1; column 5, lines 15-20; column 7, lines 11-13) converts the selenium into an organic form viz. the glycine complex of selenium, and the present method does not make provision for Fe^{3+} and Co^{2+} as Howard does.

Regarding present claim 5, Howard (column 7, line 37, line 45, line 52, line 61) utilizes chlorides of zinc, manganese and copper, which result in relatively high amounts (equivalent to the amounts of zinc, manganese and/or copper used) of sodium chloride as contaminant, whereas the present method utilizes oxides, hydroxides or carbonates

of the different elements, which after the reaction, leave as byproducts only water and/or carbon dioxide gas.

It is important to note that Howard is not capable of producing a product free of unacceptable contaminants, such as sodium and sodium chloride, whereas this is possible by the present method.

In summary, claims 1 and 3-13 are thus not anticipated or made obvious by the Howard patent, and Applicants respectfully submit that 35 U.S.C. §103(a) rejection is traversed and should be withdrawn.

In view of the foregoing, this application is in condition for immediate allowance.

Favorable consideration is respectfully requested.

Respectfully submitted,

LARSON & TAYLOR, PLC

June 25, 2002

By: _____ Reg No. 31,877
William E. Jackson
Registration No. 24,016

1199 North Fairfax Street, Suite 900
Alexandria, Virginia 22314
(703) 739-4900